

Exhibit 115



U S CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D C 20207

0 8 FEB 1988

Thomas J. Germiné, Esq.
RD 1, C53-A Laurie Court
Chester, New Jersey 07930

Dear Mr. Germiné:

Your letter to Stephen Lemberg dated December 1, 1987, concerning the request of your client, Mark Germiné, (Petition HP 87-1) that the Commission ban pulverized and granular limestone products that have more than 0.01 percent tremolite, has been forwarded to the Directorate for Health Sciences. This letter represents the views of the Directorate for Health Sciences on the scientific issues raised by this petition. I wish to emphasize that the petition has not been acted upon by the Commission.

To date, the controversy on these types of limestones has centered largely around playsand for children, and I will focus on that product in this letter. For the reasons stated below, we believe that the available data, including those submitted by Mr. Mark Germiné, are insufficient to establish a carcinogenic hazard from the tremolite found in playsand.

DIFFERENT FORMS OF TREMOLITE

Physical differences. It is well known that tremolite, and certain other minerals, can exist in either an asbestos form or a non-asbestos form, depending on the conditions of its geological formation. The non-asbestos form of tremolite is an aggregate that can cleave as readily in one plane as another. When the non-asbestos form of tremolite breaks, therefore, it forms cleavage fragments or particles, much as a large rock does when broken into smaller pieces. The asbestos form of tremolite, on the other hand, exists as bundles of thin, long fibers. These tend to break only in a single plane into smaller bundles of the thin, long fibers, until individual fibers are exposed. Once the mineral is created in its non-asbestos form, it cannot be converted to the asbestos form by weathering or use. Such

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factors, however, could increase the number of individual fibers or small bundles present in the asbestos form of tremolite.

The Commission's Health Sciences staff agrees with Mr. Mark Germiné that the presence of significant quantities of the asbestos form of tremolite in playsand would be a matter of great concern. The available data, including those cited by Mr. Mark Germiné, establish clearly the carcinogenic risk associated with exposure to the asbestos form of tremolite. However, the analyses performed on the samples of playsand from the location referred to by Mr. Mark Germiné, and on other samples of playsand obtained by the Commission, have not shown any significant presence of asbestos. The results of these tests are discussed in more detail below.

Regulatory definitions. As noted by Mr. Mark Germiné, the Occupational Safety and Health Administration (OSHA), while distinguishing between the asbestos and non-asbestos form of tremolite, has published requirements applicable to particles of either form of the mineral that meet certain dimensional criteria. 29 CFR 1910.1001 (1987). Originally, OSHA was able to issue its requirements under an initial statutory authority that enabled OSHA to mandate then-existing standards without making the sort of evidentiary determination of risk that the Commission is now required to make. The original OSHA requirements for these fibers have been litigated several times, but OSHA staff inform us that none of these cases has presented a situation where only the non-asbestos form of tremolite was involved.

In 1986, OSHA revised its requirements, and the revised requirements as originally published would apply to either the asbestos or non-asbestos forms of tremolite. However, because of the controversy about whether the non-asbestos form of tremolite presents the same types of risks as does the asbestos form of tremolite, OSHA has stayed the requirements pertaining to the non-asbestos form pending further rulemaking proceedings. 51 Fed. Reg. 37002 (Oct. 17, 1986); 52 Fed. Reg. 15722 (April 30, 1987). The Directorate is monitoring these proceedings, but further action by OSHA in this area is not expected before the summer of 1988.

TESTING OF PLAYSAND

Tests of the Germiné playsand. In his original letter to the Editor of the New England Journal of Medicine, published October 2, 1986, Mr. Mark Germiné stated that the presence of "tremolite asbestos" was "identified on the basis of its optical and x-ray diffraction properties." Commission consultants

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believe that these techniques are not adequate to determine which form of tremolite is present in the product. In order to determine whether asbestos was present, the Commission obtained samples of the playsand in question and had it tested by two contract laboratories.

The first contractor, Drs. Langer and Nolan of the Mount Sinai School of Medicine, New York, New York, concluded on the basis of polarized light microscopy and electron microscopy that the samples of playsand did not contain any asbestos. According to Drs. Langer and Nolan in their reply to Mr. Mark Germino's letter in the New England Journal of Medicine of October 2, 1986, the technique of x-ray diffraction cannot be used to distinguish the asbestos from the non-asbestos forms of tremolite. Polarized light microscopy was used by Drs. Langer and Nolan to distinguish the habits (forms) of tremolite.

Drs. Langer and Nolan also estimated that there was about 0.004-0.0001 percent of small particles, apparently non-asbestos cleavage fragments, in the playsand tested. The potential for adverse health effects from this type of particle is discussed below.

The playsand was also tested by McCrone Environmental Services of Norcross, Georgia. They found no asbestos and few cleavage fragments meeting the OSHA definition of "fiber".

In addition, the Commission's Health Sciences staff is aware of a test of the same playsand by Ann G. Wylie of the University of Maryland. She found no asbestos and estimated less than 0.5 percent tremolite. Tests of the playsand by state health departments in New York and Massachusetts also confirmed that no asbestos was present. At a special meeting held in February 1987 by the Northeast Regional Environmental Health Center in Amherst, Massachusetts, to discuss this issue, mineralogists and public health officials determined that the possibility that playsand contains asbestos fibers is extremely low.

Tests of other playsands. The Commission staff is also aware of concerns that were raised about another brand of playsand that may have contained tremolite asbestos. The distributor of that brand took the playsand off the market when these concerns were brought to its attention by Dr. Abraham of the State University of New York.

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In addition, the Commission's Health Sciences staff has tested 14 samples, involving 13 different brands, of other playsands by optical microscopy. None of these has been found to contain asbestos.

Thus, of the 15 brands of playsand that have been examined, the one that was of concern was removed promptly from the market. Of the remaining 14 brands, none was found to contain asbestos. The lack of data showing the non-asbestos form of tremolite to be hazardous is discussed in the following section.

POTENTIAL HEALTH HAZARDS OF THE NON-ASBESTOS FORM OF TREMOLITE

As far as we are aware, there are no studies in either humans or animals that demonstrate the carcinogenicity of the non-asbestos form of tremolite. Our consideration of Mr. Mark Germine's contentions in this area have been complicated by the fact that he does not distinguish between the asbestos and non-asbestos forms of tremolite, either in describing the results of his tests or in describing the findings of the literature. For example, in his letters and in the petition, he cites studies by Pooley, Davis et al., Cook et al., Yazicioglu et al., and Becklake to show the adverse effects of tremolite. However, each of these studies is known to involve exposure to the asbestos form of minerals. Therefore, in view of the known differences in the structure and other properties between the asbestos and non-asbestos forms of minerals, we do not believe that these studies can be viewed as supporting a conclusion that the non-asbestos form of tremolite presents a risk of cancer or other adverse health effects at the exposure levels that may be involved in the use of playsand. On the other hand, there are no studies sufficient to demonstrate that inhalation of the non-asbestos form of tremolite is safe.

CONCLUSION

In some instances, there may be playsand on the market that contains particles of the non-asbestos form of tremolite that meet the OSHA definition of "fiber." We do not believe that the available data are sufficient to establish that a carcinogenic or other hazard is associated with exposure to the non-asbestos form of tremolite particles. The Commission's Health Sciences staff will continue to evaluate new studies relevant to this issue and to participate in the ongoing activities of the Federal Asbestos Task Force. We will also be evaluating the evidence submitted in

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the ongoing rulemaking on the issue at OSHA. If you can provide additional factual information on the issues discussed above, I would appreciate receiving it.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Ulsamer". The signature is fluid and cursive, with the first name "Andrew" and last name "Ulsamer" clearly distinguishable.

Andrew G. Ulsamer, Ph.D.
Associate Executive Director
Health Sciences